Vitalograph BT12 ECG Regulatory Notices

Warning and Advisory Notices:

Note: *Please read all this information before using this Vitalograph device.*

A full set of warnings, advisory notices, cleaning instructions and operational instructions for this device and the PC software used with the measuring unit are available at www.vitalograph.co.uk.

- The Vitalograph Model BT12 is an active medical product and, in connection with a receiving unit, serves as a mains-independent, wireless ECG device for use by trained medical professionals.
- The ECG measuring unit is not suitable for intracardial use.
- The ECG measuring unit is not suitable for use in rescue helicopters or ambulances.
- The signals output by the measuring unit do not meet the alarm standard for medical electrical devices, DIN EN 60601-1-8.
- To guarantee patient safety, the receiver unit and peripheral devices are to be operated outside of the patient's immediate surroundings, i.e. with a minimum distance of 1.5 m to the patient.
- The ECG measuring unit is a defibrillation-proof application part of type BF. The device is not suitable for direct leads to the heart. When using a defibrillator, the ECG electrodes and the defibrillator must not come into contact.
- It is not possible to operate high frequency devices in combination with the ECG measuring device.
- When monitoring critical patients, an alternative ECG system should be kept readily available in the event the device fails.
- Only use bio-compatible and CE-approved ECG electrodes with the ECG measuring unit.
- When using the BT12 during a stress ECG, it is required that the patient be under constant observation.
- Make sure that the Bluetooth monitor to which the measured data is transmitted is invisible to other Bluetooth end devices. Otherwise, there could be errors in the data transmission.
- Only use the Bluetooth dongle certified by Vitalograph and included in delivery for Bluetooth communication
- Cleaning and disinfection (Refer to the User Training Manual for full cleaning instructions):
  - For disinfection, use Incidin® Foam or Mikrozid® AF Liquid or an equivalent means.
  - Wipe the housing with a soft, moist cloth.
  - **CAUTION:** Never submerge the device in disinfectant or other liquids. Otherwise, the device could be damaged and patients and users could be endangered.
  - To clean the electrode cable, rub the cable off with a soft, moist cloth. Only use a mild cleaning agent to avoid damage. Never submerge the cables in liquids. For disinfection, rub the cable off with a cloth soaked in Incidin® Foam or Mikrozid® AF Liquid.
  - Electrodes: If you use disposable adhesive electrodes, dispose of these immediately after use to avoid using them again by mistake.
- The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste.

Warranty

Your Vitalograph device is guaranteed for one year*. Replace if it is faulty, otherwise replace the unit every five years. Any unauthorised changes to Vitalograph device hardware or software may compromise product safety and/or data and as such Vitalograph cannot be held responsible and the device will no longer be supported.

**Excepting accidental / transit damage or inappropriate use of the device.*

FDA Notice:

Caution: Federal Law restricts this device to sale by, or on the order of a physician.

Medical Devices may be affected by cellular telephones and other personal or household devices not intended for medical facilities. It is recommended that all equipment used near the Vitalograph product comply with the medical electromagnetic compatibility standard and to check before use that no interference is evident or possible. If interference is suspected or possible, switching off the offending device is the normal solution, as is required in aircraft and medical facilities.

The BT12 device is intended for use in the electromagnetic environment specified below. The customer or user of the system should assure that it is used in such a system.

- Floors should be wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be less than 30%.
- Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
- Interference may occur in the vicinity of equipment marked with the following symbol - ((ᵛ))

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the BT12

The **BT12** is intended for use in an electromagnetic environment where radiated radio frequency (RF) signals are controlled. The customer or the user of the **BT12** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and **BT12** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter M**		
	150 kHz to 80 MHz $d = (3,5/U_1)\sqrt{P}$	**80 MHz to 800 MHz** $d = (3,5/E_1)\sqrt{P}$	**800 MHz to 2.5 GHz** $d = (7/E_1)\sqrt{P}$
0.01	0.1m	0.1m	0.2m
0.1	0.4m	0.4m	0.7m
1	1.2m	1.2m	2.3m
10	3.7m	3.7m	7.4m
100	11.7m	11.7m	23.3m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

NOTE 2 *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

NOTE 3 $U_1 = 3$*Vrms,* $E_1 = 3$ *V/m.*

Technical Specification

Product class in acc. with 93/42/ EC (MDD)	II a
Weight, incl. cable	210 g incl. batteries (154 g without batteries)
Temperature range:	**Operation:** 0 - 50 °C **Storage (without batteries):** 0 - 50 °C
Air pressure range	700 - 1060 hPa
Power supply	2* AA batteries (1.5 V) or rechargeable batteries (1.2 V)
Current consumption at 3 V	**Operation:** 148 mA **Stand-by:** 37 mA
Data transmission	Wireless, online with wireless standard Bluetooth 2.1
Intermediate data memory (data saving mode)	Is sufficient for at least 6 minutes of ECG
Classification in acc. with 60601-1 - Type of protection against el. shock - Degree of protection against el. shock	Device with internal power supply Type BF
Electromagnetic compatibility (EMC) in acc. with 60601-1-2	**Noise suppression:** EN 55011 **Immunity to interference:** EN 61000-4 parts 2, 3, 6, 8
Degree of protection against penetration of water	IPX3
Electrodes	Standard ECG electrodes
Signal output for:	Pulse frequency exceeded/fallen short of Missing signal / connection termination / electrode loss
Sound pressure level of a signal can be regulated over 5 levels	37 dB – 55 dB
Product liability	The service life of the product is 5 years.
Wireless transmission	Approved in accordance to R&TTE directive transmitter module marked by CE, manufactured by MITSUMI incorporated to OEM product.

BT12 operate safely and effectively in an environment where BT devices and WLAN devices coexist. But some restrictions have to be considered. We recommend using the BT12 device together with a maximum of two other BT devices within the range of each BT ECG device. Furthermore, any WLAN sender or receiver (e.g. WLAN USB dongles for PCs) should be placed more than 1 meter away from the BT12 and the BT receiver (BT USB dongle for PCs) respectively. Otherwise, BT12 will lose data packets. The user is responsible for ensuring that data transmission is not corrupted by too many wireless senders or receivers in the vicinity. Please refer to the User Training Manual 07657 for a trouble shooting guide for pairing the Vitalograph ECG BT12 device.

Declaration of Conformity

Product: Model 4130 Vitalograph BT12 ECG

Vitalograph hereby ensures and declares that the above product associated with this user manual, is designed and manufactured in accordance with the following QMS regulations and standards:

- FDA Quality System Regulation {QSR} 21 CFR 820.
- EN ISO 13485: 2012. Medical devices. Quality management systems. Requirements for regulatory purposes.

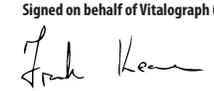
Certifying Body: British Standards Institute {BSI}.

{For 93/42/EEC and CMDR}.

BSI Notified Body #: 0086

Certificate Nos. CE 00772, CE 85553, MD 82182

Signed on behalf of Vitalograph (Ireland) Ltd.



Frank Keane, General Manager, Vitalograph (Ireland) Ltd.